

Application No. 09/744,169

August 26, 2002

In the Description

On page 1, after the title of the invention, and before the heading "Technical Field" please add the following paragraph:

C<sup>1</sup>  
- -This application claims the benefit under 35 U.S.C. § 119(a) of the filing date for Republic of Ireland application number 990406, filed on May 20, 1999, and the benefit under 35 U.S.C. § 365(a) of the filing date for PCT international application number PCT/IE00/00060, filed on May 10, 2000.- -

In the Claims

Please amend the claims as follows:

C<sup>2</sup>  
Claim 4. (Once Amended) A formulation according to claim 3, wherein the rate-controlling membrane comprises a mixture of a major proportion of a pharmaceutically acceptable film-forming, water-insoluble polymer and a minor proportion of a pharmaceutically acceptable film-forming, water soluble polymer in a selected ratio, the selected ratio of said water-insoluble polymer to said water-soluble polymer being effective to permit a SSRI release rate which allows controlled release of said SSRI over a period of not less than about 12 hours following oral administration.

C<sup>3</sup>  
Claim 23. (Once Amended) A formulation according to claim 1, wherein the SSRI release rate from the particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

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(a) no more than about 15% of the total SSRI is released after 0.5 of an hour of measurement in said apparatus;

(b) no more than about 25% of the total SSRI is released after 1 hour of measurement in said apparatus;

(c) between about 20% and about 75% of the total SSRI is released after 2 hours of measurement in said apparatus;

(d) not less than about 75% of the total SSRI is released after 4 hours of measurement in said apparatus; and

(e) not less than about 85% of the total SSRI is released after 6 hours of measurement in said apparatus.

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cont.

Claim 24. (Once Amended) A formulation according to claim 1, wherein the SSRI release rate from the particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total SSRI is released after 4 hours of measurement in said apparatus;

(b) no more than about 45% of the total SSRI is released after 6 hours of measurement in said apparatus;

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(c) between about 45% and 80% of the total SSRI is released after 8 hours of measurement in said apparatus;

C3  
cont.  
(d) not less than about 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and

(e) not less than about 80% of the total SSRI is released after 12 hours of measurement in said apparatus.

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Claim 28. (Once Amended) A formulation according to claim 25, wherein the SSRI release rate from the particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

C4  
(a) no more than about 20% of the total SSRI is released after 1 hour of measurement in said apparatus;

(b) no more than about 60% of the total SSRI is released after 2 hours of measurement in said apparatus;

(c) not less than about 20% of the total SSRI is released after 4 hours of measurement in said apparatus;

(d) not less than about 35% of the total SSRI is released after 6 hours of measurement in said apparatus;

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(e) not less than about 50% of the total SSRI is released after 8 hours of measurement in said apparatus.

(f) not less than about 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and

(g) not less than about 75% of the total SSRI is released after 12 hours of measurement in said apparatus.

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cont.

Claim 29. (Once Amended) A formulation according to claim 25, wherein the SSRI release rate from the particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 20% of the total SSRI is released after 1 hour of measurement in said apparatus;

(b) no more than about 45% of the total SSRI is released after 2 hours of measurement in said apparatus;

(c) between about 20% and about 70% of the total SSRI is released after 4 hours of measurement in said apparatus;

(d) between about 35% and about 85% of the total SSRI is released after 6 hours of measurement in said apparatus;

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(e) not less than about 50% of the total SSRI is released after 8 hours of measurement in said apparatus.

(f) not less than about 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and

(g) not less than about 75% of the total SSRI is released after 12 hours of measurement in said apparatus.

C4  
cont.

Claim 30. (Once Amended) A formulation according to claim 1, wherein the SSRI release rate from the particles exhibits the following *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 50% of the total SSRI is released after 2 hours of measurement in said apparatus;

(b) not less than about 35% of the total SSRI is released after 6 hours of measurement in said apparatus; and

(c) not less than about 80% of the total SSRI is released after 22 hours of measurement in said apparatus.

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Claim 33. (Once Amended) A method for the treatment of depression or obsessive compulsive disorder treatable with an SSRI, comprising administering to a patient

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suffering from one of said conditions a therapeutically effective amount of a  
multiparticulate controlled release SSRI formulation according to claim 1.

C<sup>5</sup>  
Cont.  
Claim 34. (Once Amended) A method for the treatment of depression or obsessive  
compulsive disorder treatable with an SSRI, comprising administering to a patient  
suffering from one of said conditions a therapeutically effective amount of a  
multiparticulate controlled release SSRI formulation according to claim 25.

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Please add the following claim:

C<sup>6</sup>  
Claim 35. (New) A formulation according to claim 3, wherein the rate-controlling  
membrane comprises a pharmaceutically acceptable film-forming, water-insoluble  
polymer in an amount effective to obtain a controlled release of a SSRI over a period of  
not less than about 12 hours following oral administration.

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